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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,695	09/30/2003	Robin D. Pierce	7133.US.O1	5085
23492	7590	08/10/2004	EXAMINER	
STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			VESTAL, REBECCA M	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,695	PIERCE ET AL.	
	Examiner	Art Unit	
	R. Michelle Vestal	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/30/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. A suggested title would be "Low volume electrochemical biosensor."

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the trigger electrode must be shown or the feature canceled from Claims 9, 11, 24 and 26. The third electrode must be shown or the feature canceled from Claims 10 and 25. The layer of mesh must be shown or the feature canceled from Claims 13 and 27. The capillary must be shown or the feature canceled from Claims 14 and 28. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate

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figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 16 is objected to because of the following informalities: Claim 16 contains two components designated part (f) (lines 17 and 25). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 5 and 20 disclose a biosensor further including at least one reagent-containing layer overlying *the conductive track leading from* the working electrode (emphasis added). Figures 1, 2, 4 and 5 clearly show the reagent-containing layer (22 and 22') overlying the working electrode (20 and 20'), not the conductive track (14a and 14a'). The specification also discloses the application of the reagent-containing layer on the surface of the working electrode (Page 13, lines 10-12 and Page 21, lines 21-25). No mention of applying the reagent-containing layer on the conductive track leading from the working electrode is made in the specifications, nor is there any explanation of how the positioning of the layer in this configuration would enable the detection of an analyte, because the conductive track is located outside of the sample reaction zone (Page 10, lines 5-9 and Page 16, lines 16-24) and, therefore, would not be exposed to the analyte.

For examination purposes, Claims 5 and 20 have been interpreted to limit the biosensor as further including at least one reagent-containing layer overlying the working electrode, as disclosed in the specifications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1 part (c) it is unclear whether the "conductive track" on line 11 is the same "conductive track" in lines 12-13. The examiner suggests inserting "first" prior to "conducting track" in line 11 and "second" prior to "conducting track" in line 12 in Claim 1 if this is what is meant.

In Claim 16 part (e) it is unclear whether the "conductive track" on line 12 is the same "conductive track" in lines 13-14. The examiner suggests inserting "first" prior to "conducting track" in line 12 and "second" prior to "conducting track" in line 13 in Claim 16 if this is what is meant.

For examination purposes, Claims 1 and 16 have been interpreted as having a first and second conductive tracks leading from the working electrode and a second electrode, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,299,757 to Feldman et al., referred to hereafter as "Feldman."

Regarding Claim 1, Feldman discloses a biosensor (Col. 1, lines 13-14) having:

- (a) an electrode support (Col. 26, lines 25-26 and Fig. 2, 38);
- (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (Col. 26, lines 22-23 and Fig. 2, 22 and 24);
- (c) a conductive track leading from the working electrode to an electrical contact associated with the working electrode and a conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and
- (d) at least one reagent incorporated in at least one of the working electrode, the conductive track leading from the working electrode to the

electrical contact associated with the working electrode, or the electrical contact associated with the working electrode (Col 21, lines 28-31).

Applicant discloses that incorporation of one reagent into the working electrode allows efficient transfer of electrons from the mediator to the bulk of the working electrode because the mediator is in direct contact with the working electrode (Page 5, lines 16-18). Because the mediator can be incorporated into the working electrode, the mediator will not diffuse out of the working electrode, and, consequently, the working electrode and the dual-purpose reference/counter electrode... can be positioned in close proximity..., without fear of the mediator migrating between the working electrode and the dual-purpose reference/counter electrode (Page 5, lines 28-34).

Feldman discloses the direct contact by chemical binding (Col. 7, lines 1-2) or immobilization of a reagent, specifically a non-leachable redox mediator (Col. 1, lines 66-67), on the working electrode to prevent leaching of the mediator into the sample (Col. 21, lines 28-31). A "non-leachable" compound is defined as a compound which does not substantially diffuse away from the working surface of the working electrode for the duration of the analyte assay (Col. 7, lines 10-13). The working and dual-purpose reference/counter electrodes (Col. 7, lines 26-30) in Feldman's biosensor are positioned in close proximity to one another (Col. 25, lines 1-4). Therefore, the reagent is considered to be incorporated in the working electrode.

Regarding Claim 2, Feldman discloses a biosensor wherein the at least one reagent comprises at least one enzyme or at least one mediator or at least one co-enzyme or at least two of the enzyme, the mediator, or the co-enzyme (Col. 21, lines 28-31).

Addressing Claim 3, Feldman discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 15, lines 20-25).

Regarding Claim 4, Feldman discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 24, lines 21-27).

Regarding Claim 5, Feldman discloses a biosensor further including at least one reagent-containing layer overlying the working electrode (Col. 8, lines 53-55 and Fig. 2, 32).

Regarding Claim 6, Feldman discloses a biosensor requiring a low volume of sample to trigger an electrochemical reaction (Col. 7, lines 52-55).

Addressing Claim 7, Feldman discloses a biosensor wherein spacing between the working electrode and the at least second electrode does not exceed 200 micrometers (Col. 24, lines 66-67 and Col. 25, lines 1-3).

Regarding Claim 8, Feldman discloses a biosensor wherein the working electrode has an area of from 0.5 mm² to 5 mm² (Col. 49, lines 7-8).

Regarding Claim 9, Feldman discloses a biosensor wherein the electrode arrangement further comprises a trigger electrode (Col. 50, lines 60-61 and Col. 51, lines 1-12).

Applicant discloses that a trigger electrode can be used to determine when the sample has been applied to the strip, thereby activating the assay protocol (Page 10, lines 19-21). The trigger electrode prevents the assay from beginning until an adequate quantity of sample has filled the reaction zone (Page 10, lines 22-24).

Feldman discloses a sensor including a fill indicator, such as an indicator electrode, that can be used to determine when the measurement zone or sample chamber has been filled (Col. 2, lines 64-67). An indicator electrode is defined as one or more electrodes that detect partial or complete filling of a sample chamber and/or measurement zone (Col. 7, lines 3-5). Therefore, Feldman's indicator electrode is interpreted to be synonymous with trigger electrode.

Addressing Claim 10, Feldman discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 49, lines 19-21).

Regarding Claim 11, Feldman discloses a biosensor wherein the electrode arrangement further comprises a fourth electrode, said fourth electrode having the function of a trigger electrode (Col. 51, lines 37-45).

Regarding Claim 12, Feldman discloses a biosensor further comprising an insulating layer overlying said electrode arrangement and said conductive tracks (Col. 8, lines 23-29 and Fig. 4, 40).

Regarding Claim 13, Feldman discloses a biosensor wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer (Col. 29, lines 47-54).

Regarding Claim 14, Feldman discloses a biosensor wherein a capillary is interposed between the electrode arrangement and the insulating layer (Col. 26, lines 58-67 or Fig. 5, 26).

Regarding Claim 15, Feldman discloses a biosensor further comprising a layer of tape overlying said electrode arrangement and said conductive tracks (Fig. 2, 30).

Regarding Claim 16, Feldman discloses a biosensor (Col. 1, lines 13-14)

having:

- (a) a first substrate having two major surfaces (Fig. 1, 38 or Fig. 3, 38);
- (b) a second substrate having two major surfaces (Fig. 1, 38 or Fig. 3, 38);
- (c) a working electrode disposed on one major surface of the first substrate (Col. 3, lines 18-19, Fig. 1, 22 or Fig. 3, 22);
- (d) at least a second electrode disposed on one major surface of the second substrate (Col. 3, lines 19-20, Fig. 1, 24 or Fig. 3, 24);
- (e) a conductive track leading from the working electrode to an electrical contact associated with the working electrode and a conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1, 22 and 24 or Fig. 3, 22 and 24);
- (f) at least one reagent incorporated in at least one of the working electrode, the conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode (Col. 21, lines 28-31).
- (g) an insulating layer disposed between said working electrode and said at least second electrode (Col. 8, line 3-29, Fig. 1, 28 or Fig. 3, 28); and
- (h) the major surface bearing the working electrode facing the major surface bearing the at least second electrode (Col. 2, lines 5-6, Fig. 1 or Fig. 3).

Regarding Claim 17, Feldman discloses a biosensor wherein the at least one reagent comprises at least one enzyme or at least one mediator or at least one co-enzyme or at least two of the enzyme, the mediator, or the co-enzyme (Col. 21, lines 28-31).

Regarding Claim 18, Feldman discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 15, lines 20-25).

Regarding Claim 19, Feldman discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 24, lines 21-27).

Regarding Claim 20, Feldman discloses a biosensor further including at least one reagent-containing layer overlying the working electrode (Col. 8, lines 53-55 and Fig. 2, 32).

Regarding Claim 21, Feldman discloses a biosensor requiring a low volume of sample to trigger an electrochemical reaction (Col. 7, lines 52-55).

Regarding Claim 22, Feldman discloses a biosensor wherein spacing between the working electrode and the at least second electrode does not exceed 200 micrometers (Col. 24, lines 66-67 and Col. 25, lines 1-3).

Regarding Claim 23, Feldman discloses a biosensor wherein the working electrode has an area of from 0.5 mm² to 5 mm² (Col. 49, lines 7-8).

Regarding Claim 24, Feldman discloses a biosensor wherein the electrode arrangement further comprises a trigger electrode (Col. 50, lines 60-61 and Col. 51, lines 1-12).

Regarding Claim 25, Feldman discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 49, lines 19-21).

Regarding Claim 26, Feldman discloses a biosensor wherein the electrode arrangement further comprises a fourth electrode, said fourth electrode having the function of a trigger electrode (Col. 51, lines 37-45).

Regarding Claim 27, Feldman discloses a biosensor wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer (Col. 29, lines 47-54 or Fig. 1, 34).

Regarding Claim 28, Feldman discloses a biosensor wherein a capillary is interposed between the electrode arrangement and the insulating layer (Col. 26, lines 58-67 or Fig. 5, 26).

Claims 1-4, 10, 12, 13 and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,129,823 to Hughes et al., referred to hereafter as "Hughes."

Regarding Claim 1, Hughes discloses a biosensor (Col. 1, lines 5-6) having:

- (a) an electrode support (Col. 2, line 10 and Fig. 1, 1);
- (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (Col. 2, lines 11-12 and Fig. 1, 4, 5 and 5a);
- (c) a conductive track leading from the working electrode to an electrical contact associated with the working electrode and a conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1, 2); and
- (d) at least one reagent incorporated in at least one of the working electrode, the conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode (Col. 4, lines 28-29).

Regarding Claim 2, Hughes discloses a biosensor wherein the at least one reagent comprises at least one enzyme or at least one mediator or at least one co-enzyme or at least two of the enzyme, the mediator, or the co-enzyme (Col. 4, lines 28-29).

Addressing Claim 3, Hughes discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 4, lines 44-45).

Regarding Claim 4, Hughes discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 4, lines 43-44).

Addressing Claim 10, Hughes discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 4, lines 20-23).

Regarding Claim 12, Hughes discloses a biosensor further comprising an insulating layer overlying said electrode arrangement and said conductive tracks (Col. 5, lines 25-26 and Fig. 1, 11).

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Regarding Claim 13, Hughes discloses a biosensor wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer (Col. 4, lines 53-54 and Fig. 1, 10).

Regarding Claim 15, Hughes discloses a biosensor further comprising a layer of tape overlying said electrode arrangement and said conductive tracks (Col. 5, lines 36-37 and Fig. 1, 13).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,571,395 to Park et al.

U.S. Patent Application No. 2002/0175075 to Deng et al.

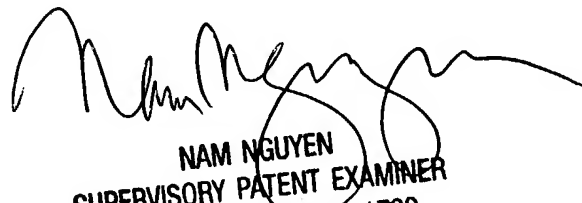
Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michelle Vestal whose telephone number is (571) 272-0524. The examiner can normally be reached on 8am-4:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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